



Livestock and Seed Program Audit, Review, and Compliance Branch Quality System Audit Report

Applicant: BIOS s.r.l.
Program : National Organic Program - Accreditation for Organic Certification
Organizations - Desk Audit
Location(s): Via Monte Grappa, 37C – 36063 Marostica (VI) Italy
Audit Date(s): December 7, 2004 - April 7, 2005
Audit File Number: NP4342KKA
Action Required: No
Auditor(s): Lauren Kavanaugh
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AUDIT ACTIVITIES

On April 7, 2005, a representative of the USDA, AMS, LS, Audit, Review and Compliance (ARC) Branch completed a review of the documentation submitted by BIOS s.r.l. for compliance to the USDA, AMS 7 CFR Part 205, National Organic Program, Final Rule. BIOS had initially submitted an application for accreditation on August 30, 2002. The application was incomplete and additional information was submitted on October 21, 2003. Many of the NOP requirements were not addressed in the resubmission. BIOS resubmitted their application for NOP accreditation in November 2004. This program was submitted to the auditor of record on November 26, 2004. Many of the applicable documents were not included in this last submission to the auditor requiring several additional submissions and clarifications of information before all of the applicable and current procedures and forms to be used in the BIOS NOP Certification Program were available for review.

Bios s.r.l. is a limited liability company operating a for-profit business with the head office located in Marostica, Italy and seven subcontracted branch offices located throughout the region. Bios application of accreditation as a certifying agent for the National Organic Program includes certification of crops, livestock, wild crops and handling operations. The NOP Standards and National List of Allowed and Prohibited Substances will be used verbatim. Applicants will be provided a copy of the NOP Rule translated into Italian; an application form; a list of documents required for admission to the control system; a contract for NOP Certification; the Technical Organic Production Norms – Consolidated text, which includes the NOP regulations, Regulation CEE 2092/91, the FIAO (Italian Federation of Organic Agriculture) guidelines, the IFOAM “Basic Standards”, along with Organic System Plan for production or processing; the Tariff list and the *Bios Informa*, a Quarterly informational bulletin printed by BIOS. The applicant also receives the *Regulation for Certification D082* which outlines the certification and inspection process in addition to providing information on the mediation and appeals process. Fees appear to be reasonable and the non-refundable portions are explained to the applicant in the *Tariff List in Force D130* and in the *Contract for the Control of Certification M012-E*. All labels are examined during the on-site inspection but are not required to be submitted prior to use.

The application review will be completed by the Control Manager according to the requirements outlined in 205.402 and the inspections will be conducted by qualified inspectors contracted by Bios. The final certification decision will be made by the President of Bios s.r.l and the Certification Commission ratifies the certification. No conflicts of interest were noted from the organizational structure. The organic certificate listed applicable information as required by the NOP Final Rule.

Job descriptions and resume information indicated that the employees of BIOS are qualified to perform NOP organic certification services. Performance evaluations are completed annually for the inspectors. All Bios employees involved in the NOP certification process have been provided training on the NOP Rule. The *Engagement Declaration M-130* addresses confidentiality, conflict of interest and consulting and is completed on an annual basis by all employees that are involved in the NOP certification process.

An annual program review of certification activities is conducted by Bios' staff that has expertise to conduct such reviews and implement measures to correct any noncompliance with the NOP rule. Inspection and testing, investigation and non-compliance procedures were listed in their procedures. Record keeping requirements and retention of records were in compliance with the NOP Rule.

BIOS s.r.l. operates as a Control and Certification Agency, certifying applicants for organic production and handling requirements in accordance with the EU Reg. CEE 2092/91 and is accredited by SINCERT in conformity to the requisites of SN UNI CEI EN 45011. BIOS is also accredited by the International Federation of Organic Agriculture Movements (IFOAM). BIOS currently certifies applicants in Italy, Romania, and the Czech Republic and intends to certify organic production operations in any foreign country where opportunities and requests arise, including Brazil, Bulgaria, Slovenia, Peru, and Egypt. Organic products certified by BIOS s.r.l. are currently exported to several European countries, the U.S.A and to Israel. BIOS has forms, procedures and documents in place that comply with the NOP rule.

FINDINGS

Bios s.r.l. has submitted the necessary documentation to satisfy the requirements of the NOP Final Rule. There were no non-compliances identified during the final desk audit of the Bios program.